

**REMARKS**

Claims 1, 3, 4 and 9-14 are pending in this application. Claims 11-14 have been withdrawn from consideration. By this Amendment, claim 9 is amended to overcome the 35 U.S.C. §112, second paragraph rejection. Support for the amendment to claim 9 can be found, for example, in the present specification at page 4, lines 5-10 and page 6, line 2 through page 8, Table 2. No new matter is added by this Amendment.

**I. Rejection Under 35 U.S.C. §112, Second Paragraph**

Claim 9 was rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite because it is allegedly unclear what the "70%" in claim 9 refers to.

Applicants have amended claim 9 to recite that the concentration of cysteine in the pharmaceutical composition after the composition is stored at 60°C for 14 days is more than 70% of an initial concentration of cysteine in the pharmaceutical composition. This amendment is supported in the specification as discussed above at page 8, Table 2. For example, the specification indicates that an initial concentration of cysteine is 100%, and that the concentration of cysteine in the pharmaceutical composition after a specific time period of storage at 60°C is less than 100% and more than 70%. Claim 9 is definite in specifying what "70%" refers to in accordance with the specification.

Withdrawal of the rejection is requested.

**II. Rejection Under 35 U.S.C. §103(a)**

The Office Action rejected claims 1, 3, 4, 9 and 10 under 35 U.S.C. §103(a) as allegedly being unpatentable over Van Rossum, et al., Review Article: Glycyrrhizin As A Potential Treatment For Chronic Hepatitis C, Aliment Pharmacol. Theor., Vol. 12, pages 199-205 (1998) ("Van Rossum") in view of U.S. Patent Application Publication No. 2002/0147201 ("Chen").

Specifically, the Patent Office alleges that Van Rossum discloses administering a glycyrrhizin solution referred to as Stronger Neo Minophagen C ("SNMC") to patients. See Van Rossum, page 203, column 1, Clinical Investigations, first paragraph. However, the Patent Office admits that Van Rossum fails to disclose the glycyrrhizin, cysteine and aminoacetic acid concentrations and the absence of sulfite recited in claims 1 and 10. See Office Action, page 5, lines 14-19.

The Patent Office thus introduces Chen as allegedly remedying the deficiencies of Van Rossum. Applicants submit that because Van Rossum and Chen do not describe similar, or even related, uses of glycyrrhizin, one of ordinary skill in the art would not have had any reason or rationale to have combined Van Rossum and Chen.

Chen describes glycyrrhizin complexed with an active agent, not glycyrrhizin as a pharmaceutical agent in its own right. For this reason, Chen specifically defines "active agent" differently than "glycyrrhizin." See Chen, paragraphs [0021], [0031] and [0049]. As such, the glycyrrhizin referred to in Chen has no intended pharmacological use as Chen specifies that the active agent (i.e., famotidine) reverse complexes from the glycyrrhizin at a low pH and thus eventually forms a protonated active ingredient that more easily dissociates in the stomach. See Chen, paragraph [0053]. Thus, Chen fails to disclose a composition having glycyrrhizin as a pharmaceutical agent, but rather as an additive to enhance delivery of other pharmaceuticals.

As such, Chen would not have provided one of ordinary skill in the art with any reason or rationale to have attempted to alter the SNMC of Van Rossum, because there is no active agent separate from glycyrrhizin in SNMC and thus no possibility to use glycyrrhizin as a complex-forming compound to enhance delivery.

Further, the Patent Office incorrectly alleges that Chen would have provided one of ordinary skill in the art with a reason or rationale to have attempted to eliminate the sulfite

from the SNMC of Van Rossum. See Office Action, page 6, line 22 through page 7, line 6. Although the Patent Office correctly notes that Chen discloses both sulfites and other preservatives (see Chen, paragraph [0059]), Chen discloses that sulfites are perfectly acceptable additives in the composition described therein. Therefore, Chen would have failed to have provided one of ordinary skill in the art with any reason or rationale to have attempted to alter the SNMC of Van Rossum to produce an injectable pharmaceutical composition that excludes sulfites, as recited in claims 1 and 10.

As such, Chen would not have provided one of ordinary skill in the art with any reason or rationale to have altered the SNMC solution of Van Rossum to (1) increase the concentration of all the active ingredients, and (2) exclude sulfite.

Withdrawal of the rejection is requested.

### **III. Rejoinder**

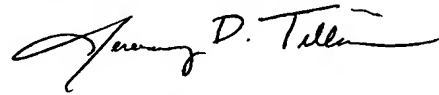
Applicants respectfully submit that claims 1, 3, 4, 9 and 10 are in a condition for allowance for at least the reasons discussed above, and therefore Applicants respectfully submit that rejoinder and consideration of withdrawn claims 11-14 is proper. MPEP §821.04 states that claims eligible for rejoinder must depend from or require all the limitations of an allowable claim. Applicants suggest that claims 11-14, drawn to methods of treating hepatic diseases or methods of treating allergy require all the limitations of independent claim 1, and therefore are eligible for rejoinder under MPEP §821.04. Accordingly, rejoinder of claims 11-14 is respectfully requested.

### **IV. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1, 3, 4 and 9-14 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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